

F. ENT COOPERATION TREA

PCT

NOTIFICATION OF THE RECORDING
OF A CHANGE(PCT Rule 92bis.1 and
Administrative Instructions, Section 422)

From the INTERNATIONAL BUREAU

To:

WALKER, Ralph, Francis
GlaxoSmithKline
Corporate Intellectual Property
(CN9.25.1)
980 Great West Road
Brentford
Middlesex TW8 9GS
ROYAUME-UNI

Date of mailing (day/month/year) 14 February 2002 (14.02.02)	IMPORTANT NOTIFICATION
Applicant's or agent's file reference RFW/P32374	
International application No. PCT/EP00/07295	International filing date (day/month/year) 27 July 2000 (27.07.00)

1. The following indications appeared on record concerning:

☐ the applicant ☐ the inventor ☒ the agent ☐ the common representative

Name and Address WALKER, Ralph, Francis SmithKline Beecham Corporate Intellectual Property Two New Horizons Court Brentford Middlesex TW8 9EP United Kingdom	State of Nationality	State of Residence
	Telephone No. 44 127 967 6336	
	Facsimile No. 44 181 975 6294	
	Teleprinter No.	

2. The International Bureau hereby notifies the applicant that the following change has been recorded concerning:

☐ the person ☐ the name ☒ the address ☐ the nationality ☐ the residence

Name and Address WALKER, Ralph, Francis GlaxoSmithKline Corporate Intellectual Property (CN9.25.1) 980 Great West Road Brentford Middlesex TW8 9GS United Kingdom	State of Nationality	State of Residence
	Telephone No. +44 208 047 5000	
	Facsimile No. +44 208 047 6894	
	Teleprinter No.	

3. Further observations, if necessary:

4. A copy of this notification has been sent to:

☒ the receiving Office ☐ the designated Offices concerned
☐ the International Searching Authority ☒ the elected Offices concerned
☐ the International Preliminary Examining Authority ☐ other:

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Authorized officer Sean Taylor
Facsimile No.: (41-22) 740.14.35	Telephone No.: (41-22) 338.83.38

P. ENT COOPERATION TREA¹

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

From the INTERNATIONAL BUREAU

To:

Commissioner
 US Department of Commerce
 United States Patent and Trademark
 Office, PCT
 2011 South Clark Place Room
 CP2/5C24
 Arlington, VA 22202
 ETATS-UNIS D'AMERIQUE
 in its capacity as elected Office

Date of mailing (day/month/year) 03 April 2001 (03.04.01)	
International application No. PCT/EP00/07295	Applicant's or agent's file reference RFW/P32374
International filing date (day/month/year) 27 July 2000 (27.07.00)	Priority date (day/month/year) 30 July 1999 (30.07.99)
Applicant CLARKE, Allan, J. et al	

1. The designated Office is hereby notified of its election made:

☒ in the demand filed with the International Preliminary Examining Authority on:

03 February 2001 (03.02.01)

☐ in a notice effecting later election filed with the International Bureau on:
2. The election ☒ was
☐ was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No.: (41-22) 740.14.35	Authorized officer Pascal Piriou Telephone No.: (41-22) 338.83.38
--	--

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

REC'D 29 OCT 2001

Applicant's or agent's file reference DM/RFW/P32374		FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/EP00/07295	International filing date (day/month/year) 27/07/2000	Priority date (day/month/year) 30/07/1999	
International Patent Classification (IPC) or national classification and IPC A61K9/48			
Applicant SMITHKLINE BEECHAM PLC et al.			



- This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
- This REPORT consists of a total of 7 sheets, including this cover sheet.

☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of sheets.

- This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☒ Certain observations on the international application

Date of submission of the demand 03/02/2001	Date of completion of this report 25.10.2001
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer Muller, I Telephone No. +49 89 2399 8716 

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/EP00/07295

I. Basis of the report

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

Description, pages:

1-30 as originally filed

Claims, No.:

1-37 as originally filed

Drawings, sheets:

1/7-7/7 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/EP00/07295

☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):
(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	37
	No:	Claims	1-36
Inventive step (IS)	Yes:	Claims	37
	No:	Claims	1-36
Industrial applicability (IA)	Yes:	Claims	1-37
	No:	Claims	

2. Citations and explanations
see separate sheet

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:
see separate sheet

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/EP00/07295

Re Item I

Basis of the report

The amendments filed with telefax dated 24.09.2001 cannot be taken into consideration in the present opinion, for following reasons:

No clear basis in the application as originally filed can be found, respectively has been indicated for the subject-matter of following amended claims:

- i) The technical features of claim 1 are extracted from multiple claims (claims 28 and 16-18, several of which refer to a multitude of other claims.
 - ii) Claim 5 is not based on the original claims, no clear basis is further apparent from the specification. Reference to cylindrical shape in the description at p. 4, for instance, relates to sub-units in general or solid sub-units.
 - iii) The same as stated under item i) applies to the dependent claims 2-4 and 6-17.
 - iv) The subject-matter of independent claim 18 introduces subject-matter going beyond the application as originally filed. Original claim 5, referring to claim 1 for instance includes precise definition of the general term sub-unit, i.e. sub-units **each selected from** capsule compartments ../... and solid sub-units ../... In contrast, new claim 18 merely defines at least one solid sub-unit, the remaining sub-units of the multi-component dosage form not being specified.
 - v) The same rationale as noted under iv) applies to new independent claim 22, with the difference that sole definition is made of the capsule compartments.
- Hence, the requirement set forth by Article 34(2)(b) PCT has not been met.

Consequently, the present international preliminary examination report is drawn up on the basis of claims 1-37 as originally filed.

Re Item V

Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Reference is made to the following documents:
D1: US-A-5 074 426 (GOODHART FRANK W ET AL) 24 December 1991 (1991-12-24)
D2: US-A-4 738 817 (WITTEWER FRITZ ET AL) 19 April 1988 (1988-04-19) cited in the application

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/EP00/07295

D3: US-A-5 674 530 (CRISON JOHN R ET AL) 7 October 1997 (1997-10-07).
D4: WO 95 16438 A (CORTECS LTD ;BARNWELL STEPHEN GEORGE (GB);
HIGGINBOTTOM SIMON (GB)) 22 June 1995 (1995-06-22) cited in the
application.

2. Novelty (Article 33(2) PCT)

Claim 1 is understood as defining a dosage form containing sub-units. Each of said sub-units being selected from i) capsule compartments, ii) solid sub-units. Each of said sub-units containing a drug substance (for the capsule compartments in view of defining the latter as that they can release **their** drug substance).

2.1 The subject-matter of the independent claim 1 is anticipated by D1 and D2:

- D1 discloses pharmaceutical capsules, dividable into individual dosage units, comprising first and second capsule units, each holding a medicinal preparation (see col. 1, l. 33-37, different sort of drugs). These capsule units representing sub-units which are connected to form an assembled dosage form. The connection being provided by an adhesive weld and/or an annular band and/or locking mechanical means (see claims 2-11). Further, the connection may be formed by a hollow cylindrical member open at one end of one capsule unit and the respectively fitting cap at one end of the other capsule unit (see claims 12-15 of D1 in view of plug and socket connectable parts).

It is further noted that for example the capsules of D1 can comprise more than two capsule compartments (see for instance figures 17 and 18), at least two of which are interchangeable, being separated by a wall; referring to figures 13 and 14, the adjacent capsule wall material may be made of hard gelatine (see col. 5, l. 13-16).

- D2 discloses pharmaceutical capsules of gelatine, comprising a plurality of capsule compartments, filled with the same or complementary drug, connected for example by means of ratchet teeth (see also figure 38; col. 12, l. 58 - col. 13, l. 5).

2.2 None of the documents cited in the international search report defines a process for manufacturing a dosage form as defined in present independent claim 37, comprising a linker having at two opposite sides plug parts which are inserted into

the open ends of the, with drug filled, capsule compartments.

Hence, the subject-matter of claim 37 is considered satisfying the requirement of Art. 33(2) PCT.

3. Inventive Step (Article 33(3) PCT)

The difference between the subject-matter of process claim 37 and the documents D1-D4 consists of the insertion of a linker having at two opposite sides plug parts into the open ends of the two capsule compartments in order to provide both assembly and closure of the two capsule compartment units.

The 'welding of the linker in place' is not considered as delimiting feature, as this step may comprise for example simply fitting of the respective sub-units in place.

The problem underlying present claim 37 is considered as providing an alternative process for the manufacture of multiple compartment dosage forms.

The use of a linker for closing and fixing two separate capsule compartments is known from D1 (see for example figure 9, however, not having the form of plug connectable parts; figures 13/14 disclosing a two piece linking element 60/64, however manufactured by filling the units 60/64 with the desired medicinal preparation, then seal with caps 62 and 66, cf. col. 4, l. 67 - col. 5, l. 4). D2 (disclosing the application of a disc-like cover plate, see for example figure 38) and D4 (using barrier material to be filled onto the first fill composition before further filling of a second fill composition, see p. 8, l. 28-32) lack the linking element for insertion into the capsule sub-units. The same as for D2 and D4 applies to D3 (one end plugging of an open first capsule half after filling with drug and an osmotic agent, the plug not functioning as two plug-part-linker, see figure-2). In view that the order of proceeding in the manufacture of a delivery system disclosed in D3 is similar to present claim 37 (see col. 2, l. 46-55), this document is considered as closest prior art.

Considering the teaching of D1-D4, no hint is apparent that would lead the skilled person to manufacture a dosage form by using a linker with, at opposite side, plug parts in order to provide a dosage form of assembled capsule compartments. Hence, claim 37 is considered satisfying the requirements of Art. 33(3) PCT.

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/EP00/07295

4. Industrial Applicability (Article 33(4) PCT)
The subject-matter of the claims 1-37 is applicable in the pharmaceutical industry.
5. A positive preliminary examination report for the dependent claims can only be established when the requirements of the PCT for the independent claims are complied with.

Re Item VIII

Certain observations on the international application

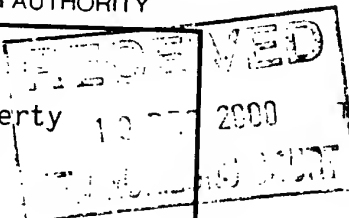
1. Claim 1 defines the sub-units of the dosage form (capsule compartments and solid sub-units) as comprising drug substance (in view of reference to capsule compartments as their drug substance), whereas in the dependent claims 3 and 6, referring to claim 1, solely part of the contained capsule compartments may contain drug substance (see one or more of the capsule compartments), and thus, leading to a lack of clarity of the subject-matter of claim 1 (Art. 6 PCT).
2. The meaning of the feature of 'the sub-units being retained together by the connection at least prior to administration' is unclear and hence, has not been taken into consideration for above assessment of novelty and inventive step.

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

PCT

To:
 SmithKline Beecham
 Corporate Intellectual Property
 Attn. WALGER, Ralph Francis
 Two New Horizons Court
 Brentford
 Middlesex TW8 9EP
 UNITED KINGDOM



NOTIFICATION OF TRANSMITTAL OF
 THE INTERNATIONAL SEARCH REPORT
 OR THE DECLARATION

(PCT Rule 44.1)

Applicant's or agent's file reference RFW/P32374	Date of mailing (day/month/year) 15/12/2000
International application No. PCT/EP 00/07295	International filing date (day/month/year) 27/07/2000
Applicant SMITHKLINE BEECHAM PLC	

1. ☒ The applicant is hereby notified that the International Search Report has been established and is transmitted herewith.
Filing of amendments and statement under Article 19:
 The applicant is entitled, if he so wishes, to amend the claims of the International Application (see Rule 46):

When? The time limit for filing such amendments is normally 2 months from the date of transmittal of the International Search Report; however, for more details, see the notes on the accompanying sheet.

Where? Directly to the International Bureau of WIPO
 34, chemin des Colombettes
 1211 Geneva 20, Switzerland
 Facsimile No.: (41-22) 740.14.35

For more detailed instructions, see the notes on the accompanying sheet.

2. ☐ The applicant is hereby notified that no International Search Report will be established and that the declaration under Article 17(2)(a) to that effect is transmitted herewith.

3. ☐ With regard to the protest against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:
- ☐ the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.

☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. **Further action(s):** The applicant is reminded of the following:

Shortly after **18 months** from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in Rules 90bis.1 and 90bis.3, respectively, before the completion of the technical preparations for international publication.

Within **19 months** from the priority date, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase until 30 months from the priority date (in some Offices even later).

Within **20 months** from the priority date, the applicant must perform the prescribed acts for entry into the national phase before all designated Offices which have not been elected in the demand or in a later election within 19 months from the priority date or could not be elected because they are not bound by Chapter II.

Name and mailing address of the International Searching Authority

European Patent Office, P.B. 5818 Patentlaan 2
 NL-2280 HV Rijswijk
 Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
 Fax: (+31-70) 340-3016

Authorized officer

Catherine Humbert

NO TO FORM PCT/ISA/220

These Notes are intended to give the basic instructions concerning the filing of amendments under article 19. The Notes are based on the requirements of the Patent Cooperation Treaty, the Regulations and the Administrative Instructions under that Treaty. In case of discrepancy between these Notes and those requirements, the latter are applicable. For more detailed information, see also the PCT Applicant's Guide, a publication of WIPO.

In these Notes, "Article", "Rule", and "Section" refer to the provisions of the PCT, the PCT Regulations and the PCT Administrative Instructions respectively.

INSTRUCTIONS CONCERNING AMENDMENTS UNDER ARTICLE 19

The applicant has, after having received the international search report, one opportunity to amend the claims of the international application. It should however be emphasized that, since all parts of the international application (claims, description and drawings) may be amended during the international preliminary examination procedure, there is usually no need to file amendments of the claims under Article 19 except where, e.g. the applicant wants the latter to be published for the purposes of provisional protection or has another reason for amending the claims before international publication. Furthermore, it should be emphasized that provisional protection is available in some States only.

What parts of the international application may be amended?

Under Article 19, only the claims may be amended.

During the international phase, the claims may also be amended (or further amended) under Article 34 before the International Preliminary Examining Authority. The description and drawings may only be amended under Article 34 before the International Examining Authority.

Upon entry into the national phase, all parts of the international application may be amended under Article 28 or, where applicable, Article 41.

When?

Within 2 months from the date of transmittal of the international search report or 16 months from the priority date, whichever time limit expires later. It should be noted, however, that the amendments will be considered as having been received on time if they are received by the International Bureau after the expiration of the applicable time limit but before the completion of the technical preparations for international publication (Rule 46.1).

Where not to file the amendments?

The amendments may only be filed with the International Bureau and not with the receiving Office or the International Searching Authority (Rule 46.2).

Where a demand for international preliminary examination has been/is filed, see below.

How?

Either by cancelling one or more entire claims, by adding one or more new claims or by amending the text of one or more of the claims as filed.

A replacement sheet must be submitted for each sheet of the claims which, on account of an amendment or amendments, differs from the sheet originally filed.

All the claims appearing on a replacement sheet must be numbered in Arabic numerals. Where a claim is cancelled, no renumbering of the other claims is required. In all cases where claims are renumbered, they must be renumbered consecutively (Administrative Instructions, Section 205(b)).

The amendments must be made in the language in which the international application is to be published.

What documents must/may accompany the amendments?

Letter (Section 205(b)):

The amendments must be submitted with a letter.

The letter will not be published with the international application and the amended claims. It should not be confused with the "Statement under Article 19(1)" (see below, under "Statement under Article 19(1)").

The letter must be in English or French, at the choice of the applicant. However, if the language of the international application is English, the letter must be in English; if the language of the international application is French, the letter must be in French.

The letter must indicate the differences between the claims as filed and the claims as amended. It must, in particular, indicate, in connection with each claim appearing in the international application (it being understood that identical indications concerning several claims may be grouped), whether

- (i) the claim is unchanged;
- (ii) the claim is cancelled;
- (iii) the claim is new;
- (iv) the claim replaces one or more claims as filed;
- (v) the claim is the result of the division of a claim as filed.

The following examples illustrate the manner in which amendments must be explained in the accompanying letter:

1. [Where originally there were 48 claims and after amendment of some claims there are 51]:
"Claims 1 to 29, 31, 32, 34, 35, 37 to 48 replaced by amended claims bearing the same numbers; claims 30, 33 and 36 unchanged; new claims 49 to 51 added."
2. [Where originally there were 15 claims and after amendment of all claims there are 11]:
"Claims 1 to 15 replaced by amended claims 1 to 11."
3. [Where originally there were 14 claims and the amendments consist in cancelling some claims and in adding new claims]:
"Claims 1 to 6 and 14 unchanged; claims 7 to 13 cancelled; new claims 15, 16 and 17 added." or
"Claims 7 to 13 cancelled; new claims 15, 16 and 17 added; all other claims unchanged."
4. [Where various kinds of amendments are made]:
"Claims 1-10 unchanged; claims 11 to 13, 18 and 19 cancelled; claims 14, 15 and 16 replaced by amended claim 14; claim 17 subdivided into amended claims 15, 16 and 17; new claims 20 and 21 added."

"Statement under article 19(1)" (Rule 46.4)

The amendments may be accompanied by a statement explaining the amendments and indicating any impact that such amendments might have on the description and the drawings (which cannot be amended under Article 19(1)).

The statement will be published with the international application and the amended claims.

It must be in the language in which the international application is to be published.

It must be brief, not exceeding 500 words if in English or if translated into English.

It should not be confused with and does not replace the letter indicating the differences between the claims as filed and as amended. It must be filed on a separate sheet and must be identified as such by a heading, preferably by using the words "Statement under Article 19(1)."

It may not contain any disparaging comments on the international search report or the relevance of citations contained in that report. Reference to citations, relevant to a given claim, contained in the international search report may be made only in connection with an amendment of that claim.

Consequence if a demand for international preliminary examination has already been filed

If, at the time of filing any amendments under Article 19, a demand for international preliminary examination has already been submitted, the applicant must preferably, at the same time of filing the amendments with the International Bureau, also file a copy of such amendments with the International Preliminary Examining Authority (see Rule 62.2(a), first sentence).

Consequence with regard to translation of the international application for entry into the national phase

The applicant's attention is drawn to the fact that, where upon entry into the national phase, a translation of the claims as amended under Article 19 may have to be furnished to the designated/elected Offices, instead of, or in addition to, the translation of the claims as filed.

For further details on the requirements of each designated/elected Office, see Volume II of the PCT Applicant's Guide.

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference RFW/P32374	<div style="display: flex; justify-content: space-between;"> <div style="width: 40%;"> FOR FURTHER ACTION </div> <div style="width: 60%; font-size: small;"> see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below. </div> </div>	
International application No. PCT/EP 00/07295	International filing date (day/month/year) <div style="text-align: center;">27/07/2000</div>	(Earliest) Priority Date (day/month/year) <div style="text-align: center;">30/07/1999</div>
Applicant SMITHKLINE BEECHAM PLC		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 3 sheets.
☒ It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

- a. With regard to the **language**, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).
- b. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international search was carried out on the basis of the sequence listing:
- ☐ contained in the international application in written form.
 - ☐ filed together with the international application in computer readable form.
 - ☐ furnished subsequently to this Authority in written form.
 - ☐ furnished subsequently to this Authority in computer readable form.
 - ☐ the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
 - ☐ the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

2. ☐ **Certain claims were found unsearchable** (See Box I).

3. ☐ **Unity of invention is lacking** (see Box II).

4. With regard to the title,

- ☐ the text is approved as submitted by the applicant.
- ☒ the text has been established by this Authority to read as follows:

MULTI-COMPONENT PHARMACEUTICAL DOSAGE FORM

5. With regard to the abstract,

- ☒ the text is approved as submitted by the applicant.
- ☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the drawings to be published with the abstract is Figure No.

- ☐ as suggested by the applicant.

☐ because the applicant failed to suggest a figure.

☐ because this figure better characterizes the invention.

☒ **None of the figures.**

INTERNATIONAL SEARCH REPORT

International Application No

/EP 00/07295

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61K9/48

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal, WPI Data, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 074 426 A (GOODHART FRANK W ET AL) 24 December 1991 (1991-12-24) column 1, line 33 - line 44 column 2, line 38 - line 42 column 4, line 1 - column 5, line 16 claims 1-14 ---	1,7, 9-11,13, 15-18
X	US 4 738 817 A (WITTWER FRITZ ET AL) 19 April 1988 (1988-04-19) cited in the application figure 38 column 3, line 54 - column 4, line 68 column 12, line 59 - column 13, line 4 column 16, line 32 - line 47 --- -/--	1

☒ Further documents are listed in the continuation of box C.☒ Patent family members are listed in annex.

* Special categories of cited documents:

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

- *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- *X* document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- *Y* document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- *G* document member of the same patent family

Date of the actual completion of the international search

8 December 2000

Date of mailing of the international search report

15/12/2000

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Muller, S

INTERNATIONAL SEARCH REPORT

International Application No

EP 00/07295

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 674 530 A (CRISON JOHN R ET AL) 7 October 1997 (1997-10-07) column 2, line 47 - line 55 -----	37
A	WO 95 16438 A (CORTECS LTD ;BARNWELL STEPHEN GEORGE (GB); HIGGINBOTTOM SIMON (GB)) 22 June 1995 (1995-06-22) cited in the application page 8, line 28 -page 11, line 12 -----	1-37

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

EP 00/07295

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
US 5074426	A	24-12-1991	AT 65907 T AU 603614 B AU 8050587 A BR 8706068 A DE 3772023 A EP 0274345 A GR 3002447 T JP 63135174 A	15-08-1991 22-11-1990 19-05-1988 21-06-1988 12-09-1991 13-07-1988 30-12-1992 07-06-1988
US 4738817	A	19-04-1988	US 4498080 A US 4655840 A CH 664938 A DE 3438235 A FR 2555972 A GB 2148235 A, B IT 1178161 B JP 5061942 B US 4738724 A BE 900950 A CH 661878 A DE 3438656 A FR 2554418 A GB 2148841 A, B IT 1178193 B JP 1947556 C JP 6073539 B JP 60132562 A	05-02-1985 07-04-1987 15-04-1988 30-05-1985 07-06-1985 30-05-1985 09-09-1987 07-09-1993 19-04-1988 30-04-1985 31-08-1987 23-05-1985 10-05-1985 05-06-1985 09-09-1987 10-07-1995 21-09-1994 15-07-1985
US 5674530	A	07-10-1997	US 5387421 A US 5976571 A	07-02-1995 02-11-1999
WO 9516438	A	22-06-1995	AU 702464 B AU 1196795 A BR 9408294 A CA 2179041 A CN 1137235 A EP 0734253 A JP 9506606 T NZ 277074 A SG 64292 A ZA 9409931 A	25-02-1999 03-07-1995 26-08-1997 22-06-1995 04-12-1996 02-10-1996 30-06-1997 26-01-1998 27-04-1999 13-06-1996

INTERNATIONAL SEARCH REPORT

Int. Application No.

PCT/EP 00/11922

A. CLASSIFICATION OF SUBJECT MATTER
 IPC 7 A61K9/48 A61K9/20

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
 IPC 7 A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
 EPO-Internal, WPI Data, PAJ, BIOSIS

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	GB 1 298 084 A (E.R.A.S.M.E.; CLAUDE R) 29 November 1972 (1972-11-29) Seite 3, Beispiel 4, Zeile 107-118 ---	1-7
Y	GB 1 355 324 A (MIDY SA; CLAUDE R) 5 June 1974 (1974-06-05) example 1 ---	1-7
A	EP 0 704 207 A (ROEHM GMBH) 3 April 1996 (1996-04-03) cited in the application examples 7-9 ---	1-7
A	EP 0 727 205 A (ROEHM GMBH) 21 August 1996 (1996-08-21) column 3, line 10 -column 3, line 28 column 9, line 56 -column 10, line 21 -----	1-7

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents:

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

T later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

X document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

Y document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

G document member of the same patent family

Date of the actual completion of the international search

28 February 2001

Date of mailing of the international search report

07/03/2001

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
 NL - 2280 HV Rijswijk
 Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
 Fax: (+31-70) 340-3016

Authorized officer

Borst, M

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/JP90/11922

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
GB 1298084	A	29-11-1972	BE 743526 A	28-05-1970
			CA 946281 A	30-04-1974
			CH 506288 A	30-04-1971
			DE 1965584 A	23-07-1970
			FR 1605150 A	16-03-1973
			IT 1044195 B	20-03-1980
			JP 48031887 B	02-10-1973
			NL 6919520 A	02-07-1970
			SE 362011 B	26-11-1973
			SU 396859 A	29-08-1973
GB 1355324	A	05-06-1974	FR 2135021 A	15-12-1972
			FR 2100561 A	24-03-1972
			BE 770162 A	01-12-1971
			CA 944689 A	02-04-1974
			CH 540046 A	15-08-1973
			DE 2137213 A	16-03-1972
			IT 1044956 B	21-04-1980
			NL 7110361 A	01-02-1972
EP 0704207	A	03-04-1996	DE 9414065 U	03-11-1994
			CZ 9502235 A	13-03-1996
			HU 75239 A	28-05-1997
			JP 8073378 A	19-03-1996
			SK 106295 A	08-01-1997
			US 5705189 A	06-01-1998
EP 0727205	A	21-08-1996	DE 29502547 U	30-03-1995
			JP 8245422 A	24-09-1996

INTERNATIONALER RECHERCHENBERICHT

Int. Internationales Aktenzeichen

PCT 00/11922

A. KLASSIFIZIERUNG DES ANMELDUNGSGEGENSTANDES
IPK 7 A61K9/48 A61K9/20

Nach der Internationalen Patentklassifikation (IPK) oder nach der nationalen Klassifikation und der IPK

B. RECHERCHIERTE GEBIETE

Recherchierte Mindestprüfstoff (Klassifikationssystem und Klassifikationssymbole)
IPK 7 A61K

Recherchierte aber nicht zum Mindestprüfstoff gehörende Veröffentlichungen, soweit diese unter die recherchierten Gebiete fallen

Während der internationalen Recherche konsultierte elektronische Datenbank (Name der Datenbank und evtl. verwendete Suchbegriffe)
EPO-Internal, WPI Data, PAJ, BIOSIS

C. ALS WESENTLICH ANGESEHENE UNTERLAGEN

Kategorie*	Bezeichnung der Veröffentlichung, soweit erforderlich unter Angabe der in Betracht kommenden Teile	Betr. Anspruch Nr.
Y	GB 1 298 084 A (E.R.A.S.M.E.; CLAUDE R) 29. November 1972 (1972-11-29) Seite 3, Beispiel 4, Zeile 107-118 ---	1-7
Y	GB 1 355 324 A (MIDY SA; CLAUDE R) 5. Juni 1974 (1974-06-05) Beispiel 1 ---	1-7
A	EP 0 704 207 A (ROEHM GMBH) 3. April 1996 (1996-04-03) in der Anmeldung erwähnt Beispiele 7-9 ---	1-7
A	EP 0 727 205 A (ROEHM GMBH) 21. August 1996 (1996-08-21) Spalte 3, Zeile 10 - Spalte 3, Zeile 28 Spalte 9, Zeile 56 - Spalte 10, Zeile 21 -----	1-7

☐ Weitere Veröffentlichungen sind der Fortsetzung von Feld C zu entnehmen

☒ Siehe Anhang Patentfamilie

* Besondere Kategorien von angegebenen Veröffentlichungen :

A Veröffentlichung, die den allgemeinen Stand der Technik definiert, aber nicht als besonders bedeutsam anzusehen ist

E älteres Dokument, das jedoch erst am oder nach dem internationalen Anmeldedatum veröffentlicht worden ist

L Veröffentlichung, die geeignet ist, einen Prioritätsanspruch zweifelhaft erscheinen zu lassen, oder durch die das Veröffentlichungsdatum einer anderen im Recherchenbericht genannten Veröffentlichung belegt werden soll oder die aus einem anderen besonderen Grund angegeben ist (wie ausgeführt)

O Veröffentlichung, die sich auf eine mündliche Offenbarung, eine Benutzung, eine Ausstellung oder andere Maßnahmen bezieht

P Veröffentlichung, die vor dem internationalen Anmeldedatum, aber nach dem beanspruchten Prioritätsdatum veröffentlicht worden ist

T Spätere Veröffentlichung, die nach dem internationalen Anmeldedatum oder dem Prioritätsdatum veröffentlicht worden ist und mit der Anmeldung nicht kollidiert, sondern nur zum Verständnis des der Erfindung zugrundeliegenden Prinzips oder der ihr zugrundeliegenden Theorie angegeben ist

X Veröffentlichung von besonderer Bedeutung: die beanspruchte Erfindung kann allein aufgrund dieser Veröffentlichung nicht als neu oder auf erfinderscher Tätigkeit beruhend betrachtet werden

Y Veröffentlichung von besonderer Bedeutung: die beanspruchte Erfindung kann nicht als auf erfinderscher Tätigkeit beruhend betrachtet werden, wenn die Veröffentlichung mit einer oder mehreren anderen Veröffentlichungen dieser Kategorie in Verbindung gebracht wird und diese Verbindung für einen Fachmann naheliegend ist

Z Veröffentlichung, die Mitglied derselben Patentfamilie ist

Datum des Abschlusses der internationalen Recherche

28. Februar 2001

Absenddatum des internationalen Recherchenberichts

07/03/2001

Name und Postanschrift der Internationalen Recherchenbehörde
Europäisches Patentamt, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax (+31-70) 340-3016

Bevollmächtigter Bediensteter

Borst, M

INTERNATIONALER RECHERCHENBERICHT

Angaben zu Veröffentlichungen, die zur selben Patentfamilie gehören

Internationales Aktenzeichen

PCT/SA/210/11922

Im Recherchenbericht angeführtes Patentdokument	Datum der Veröffentlichung	Mitglied(er) der Patentfamilie	Datum der Veröffentlichung
GB 1298084 A	29-11-1972	BE 743526 A	28-05-1970
		CA 946281 A	30-04-1974
		CH 506288 A	30-04-1971
		DE 1965584 A	23-07-1970
		FR 1605150 A	16-03-1973
		IT 1044195 B	20-03-1980
		JP 48031887 B	02-10-1973
		NL 6919520 A	02-07-1970
		SE 362011 B	26-11-1973
		SU 396859 A	29-08-1973
GB 1355324 A	05-06-1974	FR 2135021 A	15-12-1972
		FR 2100561 A	24-03-1972
		BE 770162 A	01-12-1971
		CA 944689 A	02-04-1974
		CH 540046 A	15-08-1973
		DE 2137213 A	16-03-1972
		IT 1044956 B	21-04-1980
		NL 7110361 A	01-02-1972
EP 0704207 A	03-04-1996	DE 9414065 U	03-11-1994
		CZ 9502235 A	13-03-1996
		HU 75239 A	28-05-1997
		JP 8073378 A	19-03-1996
		SK 106295 A	08-01-1997
		US 5705189 A	06-01-1998
EP 0727205 A	21-08-1996	DE 29502547 U	30-03-1995
		JP 8245422 A	24-09-1996